UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JOANNE MACSWAN,

Plaintiff,

v.

Civil Action No. 1:20-cv-01661-CCR

MERCK & CO., INC.

Defendant.

DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE OPINIONS OF PLAINTIFF'S CAUSATION EXPERTS

TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Cases

Rules

Pursuant to Federal Rules of Evidence 401, 403 and 702 and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), Defendant Merck & Co., Inc. (hereinafter, "Merck"), by its undersigned attorneys, files this memorandum in support of its motion to exclude opinions of Dr. Sam R. Morhaim, DDS and Dr. Shehzad Merchant, MD.

INTRODUCTION

Plaintiff Joanne MacSwan ("Plaintiff") alleges that Fosamax,[1] a drug she has not taken since 2006 at the latest, caused her to suffer in 2018 "osteonecrosis of the jaw and other irreversible damage to the jaw." ECF 1-1, Compl. ¶¶ 4, 40-42, ECF 18-2, Pl's Opp'n at 13 n.7. However, neither her retained expert nor any treating physician provides admissible testimony that supports her allegations. Plaintiff retained a periodontist, Dr. Sam Morhaim, to proffer a causation opinion. Dr. Morhaim's Rule 26 report (1) fails to identify a single scientific or medical study demonstrating that the amount of Fosamax last used by Plaintiff in 2006 could cause osteonecrosis of the jaw ("ONJ") twelve years later; and (2) demonstrates that Dr. Morhaim failed to apply a sound methodology to the facts of Plaintiff's case, including a failure to review key medical and dental records of the Plaintiff. At deposition, Dr. Morhaim conceded that he had not reviewed pertinent dental records and deposition testimony, nor could he identify a single scientific study to support his opinions. Dr. Morhaim's opinions, therefore; are not based on material facts, are unsupported by scientific data, and do not meet the established standards set forth in Federal Rule of Evidence 702 and Daubert.

Similarly, any causation opinion of Dr. Merchant – one of Plaintiff's treating physicians in 2018 – must also be excluded. As a treating physician, Dr. Merchant is not subject to the disclosure requirements of Federal Rule of Civil Procedure 26. Deutsch v. Novartis Pharms. Corp., 768 F.

[1] Fosamax "falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bones conditions such as osteoporosis and Paget's Disease." Compl. ¶ 17.

Supp. 2d 420, 472 (E.D.N.Y. 2011). Nevertheless, when a treating physician seeks to opine on causation, "that opinion is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation." Id. (internal quotations and citation omitted). The opinions of Dr. Merchant, who admittedly did not review any of Plaintiff's pharmacy records, dental records, or other relevant medical records, nor observe any clinical signs of bisphosphonate-related ONJ, therefore, must be excluded as unreliable pursuant to Daubert and Rule 702.

FACTUAL BACKGROUND

I. SCIENTIFIC DATA DOES NOT SUPPORT THE CONCLUSION THAT THERE IS A RELATIONSHIP BETWEEN ONJ AND REMOTE BISPHOSPHONATE USAGE.

Whether oral bisphosphonates like Fosamax, as opposed to IV bisphosphonates used with cancer patients, causes osteonecrosis of the jaw (ONJ) is an unresolved question. Osteonecrosis is a generic term to describe necrotic bone and is associated with various medical conditions. Ex. 1, Morhaim Dep. at 31:19-22, 32:4-12, 33:19-24. Osteonecrosis of the jaw (ONJ) – the condition at issue here – has been associated with numerous causes including radiation therapy of the head and neck, osteomyelitis, osteoporosis, herpes zoster infection, chemotherapy, and major trauma. In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 170 (S.D.N.Y. 2009). Of particular importance, dental bacterial infections that arise independent of bisphosphonate use can cause ONJ. Ex. 1, Morhaim Dep. at 31:19 – 32:3.

In 2003, reports described the development of ONJ among some bisphosphonate users. In re Fosamax Prods. Liab. Litig., 2011 WL 2566074, at *1 (S.D.N.Y. June 29, 2011). "The vast majority of ONJ cases have been reported in patients taking intravenously administered bisphosphonates" for cancer at doses higher than provided by Fosamax. Id. Critically, ONJ that is associated with bisphosphonates is distinctly and necessarily characterized by an area of dead

bone in the jaw that becomes exposed for at least eight weeks. In re Fosamax, 645 F. Supp. 2d at 171.

Oral bisphosphonates ingested for the purpose of prevention and treatment of osteoporosis have not been scientifically proven to cause or contribute to ONJ when the use of the bisphosphonate was remote to the onset of the ONJ, as it is in this case. There is no evidence present from any studies with a high level of scientific validity demonstrating that oral bisphosphonate usage – like that established here – increases the risk for ONJ in patients with osteopenia or osteoporosis. Ex. 2, Betts Rpt. at 3. While it is true that medical and scientific organizations have used terms such as "bisphosphonate-associated" and "bisphosphonate-related" ONJ ("BRONJ") or "medication-related" ONJ ("MRONJ"), those terms should not be interpreted as inferring or implying causality in regard to oral bisphosphonates as they use the term "related" and not "cause" and also encompass ONJ in IV bisphosphonate users. Id.

Several professional organizations have noted that a cause-and-effect relationship between bisphosphonates and ONJ has not been established. Specifically, the American Association of Oral and Maxillofacial Surgeons ("AAOMS") 2009 Position Paper on Bisphosphonate-Related Osteonecrosis of the Jaws states:

> the current level of evidence does not fully support a cause-and-effect relationship between bisphosphonate exposure and necrosis of the jaws . . . [and] the causal association between oral or IV bisphosphonates for treating osteoporosis and BRONJ is much more difficult to establish.

Ex. 3, AAOMS Position Paper, J Oral Maxillofac Surg, at 3 (2009). And in 2015, the American Society for Bone and Mineral Research Task Force on Long-Term Bisphosphonate Treatment noted that "the pathogenesis of ONJ remains unclear" and that the "incidence of ONJ in patients with osteoporosis is estimated to be between 1/10,000 and 1/100,000 and is only slightly higher than the ONJ incidence in the general population." Ex. 4, Robert A. Adler, et al., Managing

Osteoporosis in Patients on Long-Term Bisphosphonate Treatment, J Bone & Mineral Rsch, at 22, 17 (Sept. 9, 2015). Even Dr. Morhaim concedes that the prevalence of BRONJ in osteoporosis patients taking oral bisphosphonates is "very low" – specifically, 0.001 percent. See Ex. 1, Morhaim Dep. at 52:1-6.

Much of the literature attempting to link bisphosphonate use and ONJ discusses the half-life of bisphosphonates as a relevant factor. See Ex. 2, Betts Rpt. at 7. The suggestion is that because the half-life of the medicine in bone may be up to ten years, the medicine may be causing issues years after it is stopped. This point is misleading, however, because the half-life of bisphosphonates must be determined based on the specific physiologic location in question. See id. The ten-year half-life of bisphosphonates that is often referenced pertains to the half-life of bisphosphonates *buried* in the bone. See Ex. 1, Morhaim Dep. at 74:21 – 75:1. But bisphosphonates buried in the bone are not pharmacologically active. Ex. 2, Betts Rpt. at 7. Bisphosphonates are active on the *surface* of the bone where they can have contact with and be ingested by osteoclasts that are resorbing the bone. Id. The half-life of bisphosphonates on the surface of the bone is estimated to be only days to weeks, not years. Id.

II. PLAINTIFF'S MEDICAL AND DENTAL HISTORY

In 2001, Plaintiff was diagnosed with osteopenia – which is a term describing low bone mass that places a person at increased risk for fracture and development of osteoporosis. Due to that diagnosis, Plaintiff was prescribed bisphosphonate medications, including Fosamax, to prevent further loss of bone that could result in osteoporosis. Ex. 5, Murphy Dep. at 29:11-24, 49:4-8. Plaintiff's complaint initially alleged that she "was prescribed and began taking FOSAMAX in January 2009." Compl. ¶ 40. Plaintiff, however, now concedes that allegation was not accurate. Pl.'s Opp'n at 13 n.7. Indeed, Plaintiff's pharmacy records reveal otherwise.

Plaintiff used Fosamax from 2001 through 2006. Ex. 6, Independent Health Pharmacy Records. A closer look at Plaintiff's pharmacy records, further supported by her medical records, demonstrates that not only did Plaintiff last receive Fosamax in 2006, but her usage prior to 2006 was notably sporadic. Id.[2] Specifically, the pharmacy and medical records demonstrate that Plaintiff received: only twenty-four weeks-worth of Fosamax in 2003; no Fosamax in 2004; eight weeks-worth of Fosamax in 2005; only sixteen weeks of Fosamax dispensed in 2006; and no evidence of Fosamax usage after July 2006. Ex. 6, Independent Health Pharmacy Records. In addition to Plaintiff's sporadic Fosamax use, she was prescribed a low dose of only 35mg per week, which is half the normal dose. Ex. 1, Morhaim Dep. at 67:14-20.

There is no evidence that Plaintiff received Fosamax at any point after 2006. Id. at 66:4-7. Plaintiff, however, continued to use other bisphosphonates after 2006 and through June 2018 – one month after her ONJ diagnosis. The pharmacy and medical records reveal that Plaintiff received: four 70mg doses of generic alendronate in 2008; one 150mg dose of Boniva in 2011; sixty 35mg doses of Atelvia in 2013; forty-eight 35mg doses of Atelvia in 2014; twenty-four 35mg doses of Atelvia in 2015; forty-eight doses of 35mg Risedronate in 2016; forty-eight doses of 35mg Risedronate in 2017; and thirty-six 35mg doses of Risedronate in 2018. Id. at 63:23 – 64:16; Ex. 7, Wegman's Pharmacy Records; Ex. 8, Express Scripts Pharmacy Records; Ex. 6, Independent Health Pharmacy Records.

Over the years, Plaintiff presented with several reasons for poor oral and dental health. For example, Plaintiff was a long-term smoker, and her dentist, Dr. Lesinski, advised her that smoking is detrimental to dental health. See Ex. 9, Lesinski Dep. at 24:18-20. Further, medical records

[2] See also Ex. 5, Murphy Dep. at 33:1-15 ("[S]he has been really intermittent in the compliance of Foasmax."); id. at 35:20-24; 36:19 – 37:3 ("[N]or has she been taking her Fosamax. It has been almost a year, & she never filled the Rx.").

from August 2003 indicate that Plaintiff had a biopsy for a precancerous lesion in her mouth and the records suggest that she was subsequently diagnosed with throat cancer. Ex. 10, Audobon Women's Medical Associates at McSwan_AWMA 000008. Also of note, Plaintiff had a chronic condition known as xerostomia, or dryness of the mouth. Ex. 9, Lesinski Dep. at 29:10-13. Plaintiff's dentist advised her that xerostomia increases the risk and rate of dental decay. Id. at 72: 14-17.

Dr. Lesinski was Plaintiff's general dentist from 2001 until 2014. Id. at 32:19-23, 43:3-6. According to Dr. Lesinski, as of January 2001 – a date that preceded Plaintiff's use of Fosamax – Plaintiff was missing ten teeth due to decay from dental disease. Id. at 48:6-17. Dr. Lesinski confirmed that Plaintiff's "major problem was decay." Id. at 28:15-16. He also confirmed that Plaintiff never showed – either clinically or radiographically – any signs, symptoms, or other evidence of bone necrosis during the 13-year period that he was her primary dentist. Id. at 28:15-16, 39:12 – 42:8. That 13-year period, of course, covered the time when Plaintiff used Fosamax as well as the next eight years. See Ex. 6, Independent Health Pharmacy Records.

Dr. Lauren DeVantier was Plaintiff's general dentist from February 2014 through 2021. Ex. 11, DeVantier Dep. at 16:23 – 17:13. Dr. DeVantier testified that Plaintiff did not present with any clinical signs consistent with ONJ until May 2018. Id. at 63:8-13.

On May 1, 2018, Plaintiff saw Dr. DeVantier for an examination, where Plaintiff complained of a lump on her mandible on the lingual side near tooth #20. Id. at 63:23 – 64:2. Dr. DeVantier noted an 8mm diameter lesion with a central white lesion, which she described as consistent with a sinus tract as well as hard with the consistency of bone. Id. at 67:24 – 68:8. Dr. DeVantier, indicated that her diagnosis was consistent with a torus protruding the friable soft tissue of her jaw. Id. at 68:9-12. A torus is a natural bony growth on the inside of the lower jaw. Id. at

57:18-24. Plaintiff returned to Dr. DeVantier on May 10, 2018, with no complaints of pain and no evidence of necrosis on or near tooth #21. Id. at 69:17-23, 70:24 – 71:13. Dr. DeVantier testified that she did not note any exposed bone, but instead believed that Plaintiff's torus was rubbed and irritated by her denture, causing inflammation and infection. Id. at 74:1-11.

On June 29, 2018, Plaintiff went to Erie County Medical Center for a medical grade CT scan. Ex. 12, Erie County Medical Center Records, at MacSwan_ECEM 000016-22. The radiologist noted "parasymphyseal mandible, left more so than right suggest osteonecrosis although chronic osteomyelitis can have a similar CT appearance. Correlation for bisphosphonate therapy is recommended." Ex. 13, Erie County Medical Center Imaging Records, at MacSwan_ECMCImag 000006. Plaintiff was transferred to Buffalo General Hospital due to the discovery of an unrelated aneurysm. While at Buffalo General she was also seen by an infectious disease consultant, Dr. Almyroudis, on July 1, 2018, in regard to the infection in her jaw. Ex. 14, Merchant Dep. at 74:23 – 75:10, 10:9-13. On July 3, 2018, Plaintiff was seen by Dr. Almyroudis's partner, Dr. Merchant. Id. at 29:21-24. Dr. Merchant noted that Plaintiff was already being treated with antibiotics for the infection and that she had many missing teeth, but that her remaining teeth were intact and there was no swelling of the gums present. Id. at 34:13 – 35:2. Further, Dr. Merchant observed that Plaintiff's gums were viable and healthy, and no exposed bone was observed. Id. at 38:9-19.

On July 13, 2018, Plaintiff was seen by Dr. Au, an Oral and Maxillofacial Surgeon. Ex. 15, Au Dep. at 19:22-25. Plaintiff told Dr. Au that she had a history of almost twenty years of usage of Fosamax and other bisphosphonates for the treatment of osteopenia. Id. at 22:7-12. Dr. Au noted that Plaintiff reported significant improvement since being seen by Dr. Merchant and that there was no exposed bone. Id. at 24:22-25, 24:6-8. Plaintiff saw Dr. Merchant again on July

26, 2018. Ex. 14, Merchant Dep. at 55:19-24. Dr. Merchant noted that Plaintiff was feeling better and that there was no exposed bone. Id. at 57:12-15, 60:15-18.

On July 27, 2018, Plaintiff saw Dr. Au again, who noted that the patient was having no pain and was doing well. Ex. 15, Au Dep. at 27:22-24, 28:4-7. Dr. Au's exam noted no exposed bone. Id. at 28:23-25. Dr. Au also testified that Plaintiff's condition was improving after the treatment of antibiotics. Id. at 29:3-8. Plaintiff saw Dr. Au two more times, once on August 15, 2018 and once on September 28, 2018. Id. at 32:5-9, 33:12-14. Both times, Dr. Au noted that Plaintiff was stable and observed no exposed bone. Id. at 32:5-9, 33:15-19. Plaintiff saw Dr. DeVantier several more times from 2018 through 2021, and no problems, including exposed or necrotic bone or evidence of ONJ, were ever noted. See Ex. 11, DeVantier Dep. at 19:7 – 22:13, 75:11-20.

ARGUMENT

I. LEGAL STANDARD

Plaintiff bears the burden to establish both general and specific causation as part of her *prima facie* case. In re Rezulin Prods. Liab. Litig., 441 F. Supp. 2d 567, 575 (S.D.N.Y. 2006) (footnote omitted). General causation is "whether a substance is capable of causing a particular injury or condition in the general population," whereas "specific causation is whether a substance caused a particular individual's injury." In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II), 387 F. Supp. 3d 323, 336 (S.D.N.Y. 2019) (internal quotations and citations omitted), aff'd, 982 F.3d 113 (2d Cir. 2020). In pharmaceutical products liability cases, evidence supporting a finding of general and specific causation must be supported by admissible expert testimony. In re Mirena IUD Prods. Liab. Litig., 202 F. Supp. 3d 304, 311 (S.D.N.Y. 2016) ("'[C]ases involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person,' and thus expert testimony is

required.") (alteration in original) (citation omitted), aff'd, 713 F. App'x 11 (2d Cir. 2017). This burden is not satisfied merely by an expert's "say-so." See, e.g., Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("If the [expert] witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts); Gen. Elec. Co. v. Joiner, 522 U.S. 136, 137 (1997) ("Nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

The District Court must ensure that experts are employing "in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999). "[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony." In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 412-13 (S.D.N.Y. 2016) (quoting Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002)). While the standard of admissibility might be "liberal," trial courts must still ensure that all scientific testimony or evidence admitted is not only relevant, but reliable. In re Mirena, 169 F. Supp. 3d at 411-12. To be admissible, an expert's opinions must be supported by "good grounds," such as "data, testing methodology[,] empirical evidence" or citations to "published authority." Nook v. Long Island R.R. Co., 190 F. Supp. 2d 639, 642 (S.D.N.Y. 2002) (internal quotations and citation omitted). Indeed, speculative opinions which do not cite to any sources do not have "sufficient indicia of reliability." In re Mirena, 169 F. Supp. 3d at 455. Neither Dr. Morhaim's nor Dr. Merchant's opinions measure up to this standard.

II. EXPERT OPINION OF DR. MORHAIM

A. Dr. Morhaim Fails to Offer a Reliable Scientific Basis For His Causation Opinion.

Dr. Morhaim's opinion that Plaintiff's sporadic use of half-dose Fosamax from 2001 to 2006 caused Plaintiff to develop ONJ in 2018 is not supported by a reliable scientific basis. Preliminarily, Dr. Morhaim's report fails to identify a single published study or report to support his conclusions. See Ex. 16, Morhaim Rpt. at 3-4. In his deposition, Dr. Morhaim confirmed that his report reflected all the data he was relying upon, thereby conceding that he in fact had ***no data*** to support his opinions.[3] Dr. Morhaim's opinion consists of nothing more than conclusory statements, unsupported by facts or data, that thereby fails under Rule 702 and Daubert. See In re Mirena, 169 F. Supp. 3d at 458 ("Although Dr. Strassberg is a qualified OB/GYN, his expert opinion in this instance consists of nothing more than conclusory statements, which fails under Rule 702 or Daubert."); Hilaire v. Dewalt Indus. Tool Co., 54 F. Supp. 3d 223, 244 (E.D.N.Y. 2014) (finding expert report lacking sufficient detail for court to consider reliability and "consist[ing] primarily of conclusory statements").

i. Dr. Morhaim cannot point to a modicum of evidence that Fosamax, or bisphosphonates in general, increase the risk of ONJ more than two years after a patient ceases usage.

Dr. Morhaim concedes that he is unaware of any scientific studies or evidence indicating that a bisphosphonate last used ten years, ***or even two years***, before a patient developed ONJ could be a cause for the ONJ:

> Q: Now are you aware of any studies, epidemiologic studies or clinical studies indicating that a patient off a bisphosphonate for 10 years is at an increased risk for osteonecrosis of the jaw?

[3] See Ex. 1, Morhaim Dep. at 19:1-6 ("Q: Understood. And I'm not so much focusing on whether you'll have additional opinions. But I'm saying for the opinions that are provided in this report, all the data that you're relying upon is disclosed in this report? A: Correct.").

A: No.

Q: Are you aware of any epidemiologic studies [or] other controlled studies indicating that patients off a bisphosphonate for five years are at an increased risk for osteonecrosis of the jaw?

A: No.

Q: Are you aware of any scientific studies, clinical studies, epidemiologic studies indicating that a patient off of a bisphosphonate for two years is at an increased risk for osteonecrosis of the jaw?

A: No.

Ex. 1, Morhaim Dep. at 69:2-16.

Relevant here, Plaintiff has not ingested Fosamax since 2006, *at least* twelve years prior to the onset of her alleged ONJ. Ex. 6, Independent Health Pharmacy Records; see also Ex. 1, Morhaim Dep. at 64:23 – 65:2. It is well established that an expert cannot reply upon bald assertions to support a finding of causation. See Joiner, 522 U.S. at 146. And an expert who does not rely on any "peer-reviewed studies, scientific or testing evidence, or any principles or methodology," must be excluded because his opinion is not based on sufficient facts or data. See Leavitt v. Ethicon, Inc., 2021 WL 3674067, at *4 (D. Vt. Aug. 19, 2021) (excluding expert's opinion where he did not rely on any peer-reviewed studies, scientific or testing evidence, or any principles or methodology).

ii. Dr. Morhaim concedes that no evidence demonstrates an increased risk of ONJ in a patient receiving a 35 mg dose of Fosamax.

Dr. Morhaim also fails to account for the fact that Plaintiff was receiving a 35mg dosage of Fosamax, half of the standard dose. Ex. 1, Morhaim Dep. at 67:14-20. During his deposition, Dr. Morhaim conceded that any potential risk for ONJ in a patient taking a 35mg dosage is less

than that of a patient taking a 70mg dosage. Id. at 67:21 – 68:1. Dr. Morhaim also admitted that he is not aware of any scientific evidence to support the opinion that a 35mg dosage of Fosamax would increase the risk of ONJ at all:

> Q: Are you [a]ware of any epidemiologic evidence indicating that 35 milligrams of Fosamax puts someone at an increased risk for ONJ?
>
> A: No.
>
> Q: Have you seen in the peer reviewed publications even a case report or a case series of someone developing osteonecrosis of the jaw as a result of 35 milligrams of Fosamax?
>
> A: No.

Id. at 68:2-10.

Dr. Morhaim cannot identify any "sufficient facts or data" demonstrating that bisphosphonates cause an increased risk of ONJ ten years after usage. Further, Dr. Morhaim concedes that there is no scientific data to support the conclusion that a dosage of 35mg per week of Fosamax, the dosage Plaintiff received, results in an increased risk of ONJ. Both of these holes in Dr. Morhaim's analysis demonstrate that there is no basis for his specific causation opinion that Fosamax caused Plaintiff to develop ONJ. See Leavitt, 2021 WL 3674067, at *4.

B. Dr. Morhaim failed to apply sound methodology to the facts of Plaintiff's case – resulting in an unreliable causation opinion.

Not only must an expert rely upon sound scientific data in forming his opinion, but he must also apply it reliably to the facts of the case. See Amorgianos, 303 F.3d at 269 (affirming exclusion of proffered expert who "fail[ed] to apply his stated methodology reliably to the facts of the case") (internal quotations and citations omitted); In re Zyprexa Prods. Liab. Litig., 2009 WL 1357236, at *3 (E.D.N.Y. May 12, 2009) (excluding expert testimony where he did not "appl[y] the

principles and methods reliably to the facts of the case") (internal quotations and citations omitted). Dr. Morhaim has not done so.

i. The conceded definition of BRONJ is exposed bone for a period of eight weeks – an observation no medical provider has made regarding Plaintiff.

As noted supra, the *sine qua non* of ONJ associated with bisphosphonates is exposed bone of either the mandible or maxilla that persists for more than eight (8) weeks. Ex. 3, AAOMS Position Paper, J Oral Maxillofac Surg, at 3 (2009). Dr. Morhaim recognizes that exposed bone for eight weeks is a necessary requirement of a BRONJ diagnosis:

> Q: But in order to be in this first stage . . . you still have to have the presence of exposed bone recognized by a physician for eight weeks?
>
> A: Recognized by a dentist.
>
> Q: For eight weeks?
>
> A: Yes.
>
> Q: Okay. And you would agree with me that if you do not have exposed bone for eight weeks, you cannot have this first stage of BRONJ?
>
> A: That's the criteria we follow, yes.

Ex. 1, Morhaim Dep. at 31:2-12.

The first time that Plaintiff was noted to have any exposed bone in the jaw was on May 1, 2018 by Dr. DeVantier. Id. at 62:5-17. Just nine days later, on May 10, 2018, Dr. DeVantier examined Plaintiff again and did not note the presence of any exposed bone. Ex. 11, DeVantier Dep. at 71:24 – 72:8. Subsequently, Dr. Merchant examined Plaintiff on two separate occasions, July 3, 2018, and July 26, 2018, and did not observe exposed bone during either exam. Ex. 14, Merchant Dep. at 39:1-5, 60:15-18. Based on the testimony of Dr. DeVantier and Dr. Merchant,

the only permissible conclusion is that Plaintiff never satisfied the basic requirement of a BRONJ diagnosis—exposed bone for eight weeks. Put simply, there is "too great an analytical gap between the data and the opinion proffered." Joiner, 522 U.S. at 146.

ii. Dr. Morhaim did not review key medical and dental records or rule out plausible alternative causes in forming his opinion – two necessary steps in arriving at a reliable specific causation opinion.

Further, Dr. Morhaim admitted during his deposition that he failed to review all of Plaintiff's relevant medical records when forming his opinion. See Ex. 1, Morhaim Dep. at 54:20 – 55:10. As of January 20, 2001, Plaintiff was missing ten teeth. Ex. 9, Lesinski Dep. at 48:6-17. Those teeth were lost *prior to* Plaintiff's first use of Fosamax in January 2001 and could not have had anything to do with her Fosamax usage. Ex. 6, Independent Health Pharmacy Records. Dr. Morhaim did not review any of Dr. Lesinski's pre-2010 records, and consequently was not even aware that Plaintiff was missing 10 teeth before she even started on Fosamax. See Ex. 16, Morhaim Rpt. at 3; Ex. 1, Morhaim Dep. at 54:13-19. As a result, Dr. Morhaim did not have the full scope of Plaintiff's dental history to consider as part of his analysis in forming his opinion that Plaintiff's condition was BRONJ caused by her Fosamax usage. Such an uninformed analysis cannot possibly meet the standard of Rule 702, which requires any principles and methodology to be applied reliably to the facts of the instant case. Fed. R. Evid. 702(a)-(d); see also Israel v. Spring Indus., Inc., 2006 WL 3196956, at *4 (E.D.N.Y. Nov. 3, 2006) (acknowledging "gaps" in expert's analysis where the expert failed to review all relevant medical records and consult the patient's family history).

Additionally, Dr. Morhaim did not assess and rule out other potential causes of Plaintiff's poor dental health. "To establish specific causation, other possible causes for the symptoms experienced by plaintiff should be excluded by performing a 'differential diagnosis' . . . [which]

typically includes a physical examination, clinical tests, and a *thorough case history*." Zwillinger v. Garfield Housing Corp., 1998 WL 623589, at *19 (E.D.N.Y. Aug. 17, 1998) (emphasis added) (internal citations omitted). After close review, the expert must then rule out the obvious alternative causes, providing a reasonable explanation for doing so. DeRienzo v. Metro. Transp. Auth., 694 F. Supp. 2d 229, 236, 239 (S.D.N.Y. 2010) (excluding expert's opinion where the expert failed to rule out any possible alternative causes of plaintiff's injury).

The record suggests that Plaintiff's history of smoking and xerostomia diagnosis are both likely alternative causes of decay and dental abscesses, either of which could have led to Plaintiff's condition in 2018. Ex. 1, Morhaim Dep. at 95:10-13, 95:21 – 96:5. Indeed, Plaintiff's own dentist testified that Plaintiff's "major problem was decay." Ex. 9, Lesinski Dep. at 28:15-16. Partial dentures wearing away at friable tissue over time is also a possible cause of gum tissue breaking away, such as that allegedly experienced by Plaintiff in 2018. Ex. 1, Morhaim Dep. at 86:4-20.

Dr. Morhaim fails to explain how the relevant risk factors and alternate potential causes were ruled out to form the basis for his conclusion that bisphosphonates, and specifically Fosamax last used in 2006, were the cause of Plaintiff's oral health problems in 2018. It is simply not possible that Dr. Morhaim engaged in the required "thorough case history" when he did not even review the bare minimum of relevant records from Plaintiff's treating dentist during the initial years of her Fosamax usage. See Zwillinger, 1998 WL 623589, at *19; Ex. 1, Morhaim Dep. at 55:4-7. And while Dr. Morhaim does not need to rule out every potential cause of Plaintiff's oral health problems in reaching his opinion, he "must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." Israel, 2006 WL 3196956, at *5. Here, Dr. Morhaim has provided no explanation as to why or how he ruled out the possible alternative causes of Plaintiff's complications, but instead

provides a conclusory, unsupported opinion that Plaintiff's BRONJ was related to her sporadic, dated Fosamax use. Ex. 16, Morhaim Rpt. at 8.

Also absent from Dr. Morhaim's opinion is any explanation as to how Plaintiff's use of bisphosphonates other than Fosamax from 2008 through 2018 affected his analysis and conclusions. Plaintiff used four other bisphosphonates in the twelve years leading up to her ONJ diagnosis in 2018 – none were Fosamax. Dr. Morhaim's failure to rule out the continued use of non-Fosamax bisphosphonates as plausible alternative causes requires exclusion of his opinion. See N.K. by Bruestle-Kumra v. Abbott Lab'ys, 2017 WL 2241507, at *5-6 (E.D.N.Y. May 22, 2017) (excluding expert testimony where expert "failed to adequately investigate or eliminate potential genetic causes before arriving at her opinion"), aff'd, 731 F. App'x 24 (2d Cir. 2018).

There are a myriad of reasons to exclude Dr. Morhaim's causation opinion, each one boiling down to a failure to meet the requisite standard of reliability required under Rule 702 and Daubert. The conspicuous gaps between the scientific data, the facts in this case and Dr. Morhaim's analysis and conclusions demonstrate that his opinions lack the scientific validity required of expert testimony and "the trial court is no place for pure theory, hypothesis, or even sincerely held opinion." Colon v. Abbott Lab'ys, 397 F. Supp. 2d 405, 418 (E.D.N.Y. 2005).

III. OPINION OF DR. MERCHANT

Any causation opinion by Dr. Merchant should also be excluded.

Dr. Merchant was Plaintiff's treating physician and, generally, a treating physician may provide expert testimony regarding a patient's illness, including the cause of the illness. Deutsch, 768 F. Supp. 2d at 472 (internal quotations and citation omitted). However, a treating physician seeking to opine on causation is subject to "the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation." Id. (internal

quotations and citations omitted). Therefore, Dr. Merchant's opinions on causation must be based on "good grounds" and have "sufficient indicia of reliability" such as citations to published sources or scientific studies. Nook, 190 F. Supp. 2d at 642; In re Mirena, 169 F. Supp. 3d at 455.

First, Dr. Merchant testified that he is not an expert well-versed in the field of ONJ or its potential causes. Ex. 14, Merchant Dep. at 21:22 – 22:15. Dr. Merchant also conceded that he has not received any formal training as either a dentist or an oral surgeon. Id. at 22:16-22. Moreover, Dr. Merchant testified that he did not treat Plaintiff to make a diagnosis of BRONJ, but rather only a complication from that diagnosis. Id. at 16:8-15. This Court should exclude the opinions of Dr. Merchant on these grounds alone. See Deutsch, 768 F. Supp. 2d at 473.

Second, Dr. Merchant's opinions as to causation are not reliable, as he does not have a sufficient factual or scientific bases to support his opinions. Id. at 472. Dr. Merchant did not review Plaintiff's full medical or dental records relevant to her dental health and history. Ex. 14, Merchant Dep. at 30:17 – 31:4. Dr. Merchant does not know when or how long Plaintiff took Fosamax. Id. at 47:15 – 48:15. Dr. Merchant never spoke to either Dr. Lesinski or Dr. DeVantier, Plaintiff's two treating dentists, about her overall dental health, nor did he review their records. Id. at 30:1-16. Dr. Merchant noted that Plaintiff had missing teeth but could not say when those teeth went missing, or the causes related to them. Id. at 35:8-17. Dr. Merchant's failure to perform a thorough analysis of Plaintiff's relevant medical and dental history is another reason in favor of excluding his opinion. See Devito v. Smithkline Beecham Corp., 2004 WL 3691343, at *5 (N.D.N.Y. Nov. 29, 2004) (excluding specific causation opinion where expert did not perform reliable differential diagnosis based on a "thorough case history") (internal citations omitted); N.K. by Bruestle-Kumra, 2017 WL 2241507, at *5-6 (excluding expert testimony where expert "failed to adequately investigate or eliminate potential genetic causes before arriving at her opinion").

Like one of the treating physicians at issue in Deutsch, Dr. Merchant did not even form his own diagnosis. See Deutsch, 768 F. Supp. 2d at 474 ("[A]lthough Dr. Berg may have been the first doctor to tell Mrs. Deutsch that her condition was likely BRONJ [], he testified that his diagnosis was not based on his own analysis . . . ."). Dr. Merchant conceded that the diagnosis of BRONJ was made prior to his examination of Plaintiff:

> Q: Do you feel, Doctor, that you did an exhaustive review of the literature related to the topic of bisphosphonates and osteonecrosis of the jaw?
>
> A: At the time when I had seen the patient, I had reviewed some literature with regards to this. I cannot recall all the papers that I reviewed at that time. This was three years ago.
>
> *This was a diagnosis made before we saw the patient*. We saw the patient primarily for a complication of this diagnosis, not this diagnosis itself.

Ex. 14, Merchant Dep. at 15:20 – 16:11 (emphasis added).

In fact, Dr. Merchant could not have made a diagnosis of ONJ as he never saw exposed bone in Plaintiff's jaw. As noted, Dr. Merchant examined Plaintiff twice: once on July 3, 2018 and again on July 26, 2018. During those exams, Dr. Merchant did not personally see or identify any exposed bone, dead bone, or dead tissue in Plaintiff's mouth. Id. at 38:13 – 39:5, 60:15-18, 61:2-5. Put simply: at no point in his treatment of Plaintiff did Dr. Merchant observe exposed bone for a period longer than eight weeks, as required by the accepted definition of BRONJ. Id. at 69:12-16. And Dr. Merchant did not verify for how long, or even when, Plaintiff had taken Fosamax. Id. at 48:4-15.[4] Therefore, Dr. Merchant does not rely upon sufficient facts or data to opine that Plaintiff suffered from ONJ caused by her Fosamax usage. Nor does he apply a reliable

[4] Notably, Dr. Merchant also never directly correlated Plaintiff's alleged ONJ with her usage of Fosamax as opposed to her usage of other bisphosphonates. Id. at 47:15 – 48:15.

methodology to the facts of this case. For all these reasons, Dr. Merchant's opinion must be excluded.

CONCLUSION

For the foregoing reasons, Merck respectfully requests that the Court exclude the opinions of Dr. Morhaim and Dr. Merchant pursuant to Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993) and Federal Rules of Evidence 401, 403 and 702.

Respectfully submitted,

/s/ Robert G. Scumaci
Robert G. Scumaci, Esq.
Gibson, McAskill & Crosby, LLP
69 Delaware Avenue, Suite 900
Buffalo, New York 14202
(716) 856-4200

AND

/s/ Stephen E. Marshall
Stephen E. Marshall, Esq.
Venable LLP
750 E. Pratt Street, Suite 900
Baltimore, MD 21202
SEMarshall@Venable.com
Phone: 410-244-7407
Facsimile: 410-244-7742

Attorneys for Defendant Merck & Co., Inc.